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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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ALPHATEC SPINE, INC.
5818 EL CAMINO REAL
CARLSBAD, CA 92008

EXAMINER

SCHILLINGER, ANN M

ART UNIT	PAPER NUMBER
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3774

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/720,656	Applicant(s) FREY ET AL.	
	Examiner ANN SCHILLINGER	Art Unit 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17,22,23,26-31,34,37-39 and 58-77 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17,22,23,26-31,34,37-39 and 58-77 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17, 22, 23, 26, 34, 37-39, and 66-68 are rejected under 35 U.S.C. 102(b) as being anticipated by Barlow et al. (US Pat. No. 2,623,517). Barlow et al. discloses the following of claim 17: a surgical instrumentation system comprising: a frame (10) including multiple portions lying in at least one plane; and a plurality of retractors (11 to I6) attachable to said frame portions (Figs. 1), each of said retractors including a blade portion (21, 28) extending transversely to said at least one plane when attached thereto, said blade portion including a tissue contacting surface (posterior surface of 21, 28) adapted to contact and retract tissue from the surgical approach; at least one adjustment mechanism (18) engageable with at least one of said retractors wherein said at least one adjustment mechanism includes a shaft (40) within a securement device (42) pivotally coupled with at least one of said retractors at a pivoting coupling location (located in Fig. 4, near element 37) adjacent a proximal end of said at least one of said retractors (Figs. 1 and 4) said pivoting coupling location toward said frame portions and said securement device movable along said frame portions, the securement device operable to engage said adjustment mechanism to said frame portion (col. 4, lines 1-45).

Barlow et al. discloses the following of claim 22: the system of claim 17, wherein said adjustment mechanisms each including a first condition in locking engagement with said

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respective frame portion to fixedly secure said adjustment mechanism relative to said frame portions (col. 3, lines 40-65), said adjustment mechanisms further each including a second condition in which at least one of said retractor is in pivotal engagement with said respective adjustment mechanism to permit said retractor to pivot relative to said frame (col. 1, line 49 through col. 2, line 20).

Barlow et al. discloses the following of claim 23: the system of claim 22 further comprising clamping devices (28, 32) mounted to said frame portions and releasably engagable to respective ones of said adjustment mechanisms.

Barlow et al. discloses the following of claim 26: the system of claim 22, wherein said adjustment mechanisms each include: an adjustment handle (47); a shaft assembly (left-side assembly of Fig. 4) extending from said adjustment handle and including said shaft and an engagement member (44) at an end of said shaft assembly opposite said adjustment handle (Fig. 4).

Barlow et al. discloses the following of claim 34: the system of claim 17 wherein at least one of said retractors include a first side defining a tissue contacting surface (posterior surface of 28) and an opposite second side configured to accommodate and support surgical instruments positioned therealong.

Barlow et al. discloses the following of claim 37: the system of claim 17, wherein at least one said retractors include a blade portion defining a substantially flat tissue contacting surface (posterior surface of element 28) extending along a longitudinal axis of said blade portion, and at least another of said retractors include a blade portion defining a concave tissue contacting

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surface extending along a longitudinal axis of said at least another said retractor (posterior surface of element 21).

Barlow et al. discloses the following of claim 38: the system of claim 37, wherein said frame includes a first portion lying in a first plane and a second portion lying in a second plane that is transversely oriented to the first plane (Fig. 1).

Barlow et al. discloses the following of claim 39: the system of claim 38, wherein one or more of said retractors is attachable to said first portion and one or more of said retractors is attachable to said second portion (col. 1, line 49 through col. 2, line 20).

Barlow et al. discloses the following of claim 66: the system of claim 17, wherein in an operative position includes a medial portion adapted to lie along the posterior side of the spine, a caudal portion proximate one end of the medial portion and a cephalad portion proximate a second end of the medial portion (Fig. 1).

Barlow et al. discloses the following of claim 67: the system of claim 66, wherein in said operative position at least one of said plurality of retractors is attachable to said medial portion and is positionable adjacent the spinal mid-line, least one of said plurality of retractors is attachable to said caudal portion and is positionable in a caudal orientation relative to the spine, and least one of said plurality of retractors is attachable to said cephalad portion and is positionable in a cephalad orientation relative to the spine (Fig. 1).

Barlow et al. discloses the following of claim 68: the system of claim 17, further comprising one or more brackets (19) coupled to at least one frame portion configured to attach to a surgical table securing arm to support the system.

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Claims 17, 22, 23, 26-31, 34, 37-39, and 58-77 are rejected under 35 U.S.C. 102(b) as being anticipated by Gauthier (US Pat. No. 3,695,890). Gauthier discloses the following of the claims 17 and 37-39: a surgical instrumentation system comprising: a frame (F) including multiple portions lying in at least one plane; and a plurality of retractors (A, A', B, B') attachable to said frame portions (Figs. 1-2), each of said retractors including a blade portion (B, B') extending transversely to said at least one plane when attached thereto, said blade portion including a tissue contacting surface (posterior surface of B, B') and an opposite second side (superior surface); at least one adjustment mechanism (Figs. 7, 15) engageable with at least one of said retractors wherein said at least one adjustment mechanism includes a shaft (68) within a securement device (10) pivotally coupled with said retractors at a pivoting coupling location adjacent a proximal end of said at least one of said retractors (Fig. 1a) said pivoting coupling location toward said frame portions and said securement device movable along said frame portions, the securement device operable to engage said adjustment mechanism to said frame portion (col. 4, lines 6-36).

Gauthier discloses the following of claim 22: the system of claim 17, wherein said adjustment mechanisms each including a first condition in locking engagement with said respective frame portion to fixedly secure said adjustment mechanism relative to said frame portions, said adjustment mechanisms further each including a second condition in which at least one of said retractor is in pivotal engagement with said respective adjustment mechanism to permit said retractor to pivot relative to said frame (col. 1, lines 34-47; col. 5, line 65 through col. 6, line 20).

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Gauthier discloses the following of claim 23: the system of claim 22 further comprising clamping devices (11) mounted to said frame portions and releasably engagable to respective ones of said adjustment mechanisms.

Gauthier discloses the following of claim 26: the system of claim 22, wherein said adjustment mechanisms each include: an adjustment handle (10, 68); a shaft assembly (Fig. 15) extending from said adjustment handle and including said shaft and an engagement member (11, 13) at an end of said shaft assembly opposite said adjustment handle (Fig. 4).

Gauthier discloses the following of claim 27: the system of claim 26, wherein said engagement member includes a number of teeth (12) configured to selectively interdigitate and lockingly engage a number of teeth (on elements 13) provided adjacent a proximal end of said retractor, said number of teeth engaging one another along concave-convex pivot path of said retractor (Fig. 16).

Gauthier discloses the following of claim 28: the system of claim 27, wherein said shaft assembly includes an outer shaft (M) and an inner shaft (A) movably positioned within said outer shaft, said engagement member extending from a distal end of said inner shaft.

Gauthier discloses the following of claim 29: the system of claim 28, wherein said adjustment handle is linked with said inner shaft, said adjustment handle being rotatable to non-rotatably and linearly advance said inner shaft and said engagement member between said first condition and said second condition (col. 6, lines 47-66).

Gauthier discloses the following of claim 30: the system of claim 27, wherein said adjustment mechanism includes a pair of plates (M) at a distal end thereof, and each of said

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retractor includes a pair of proximal flanges (54, at the location of label B') pivotally coupled to said pair of plates (Fig. 17).

Gauthier discloses the following of claim 31: the system of claim 30, wherein: each flange of said pair of proximal flanges includes an arcuate slot (where element 49 passes through) defining a pivot path of the respective said retractor; said engagement member includes a slot (where element A passes through) extending along a longitudinal axis of said shaft assembly; and said adjustment mechanism further comprises a roller pin (61).

Gauthier discloses the following of claim 34: the system of claim 17 wherein at least one of said retractors include a first side defining a tissue contacting surface (posterior surface of 28) and an opposite second side configured to accommodate and support surgical instruments positioned therealong.

Gauthier discloses the following of claim 58: a surgical instrumentation system to provide a surgical approach to a patient's spine, comprising: a frame (F) including multiple portions lying in at least one plane; a plurality of retractors (A, A', B, B') attachable to said frame portions, each of said retractors including a blade portion (B, B') extending transversely to said at least one plane, said blade portion including a tissue contacting surface (posterior surface of elements B, B') adapted to contact and retract tissue from the surgical approach; and at least one adjustment mechanism (Figs. 7, 15) coupled to respective ones of said plurality of retractors; said adjustment mechanisms each including a first condition in locking engagement with said respective adjustment mechanism, said adjustment mechanisms further each including a second condition in which at least one of said retractor is in pivotal engagement with said respective adjustment mechanism to permit said retractor to pivot relative to said frame (col. 1, lines 34-47;

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col. 5, line 65 through col. 6, line 20) wherein said adjustment mechanisms each include: an engagement member (F, 13) at a distal end thereof including a number of teeth (12) configured to selectively interdigitate and lockingly engage a number of teeth (on elements 13) provided adjacent a proximal end of said retractor, said number of teeth engaging one another along concave-convex pivot path of said retractor; and a pair of plates (at the location of label B', 54) at said distal end of said adjustment mechanism and said retractor includes a pair of proximal flanges (58) pivotally coupled to said pair of plates.

Gauthier discloses the following of claim 59: the system of claim 58, wherein: each flange of said pair of proximal flanges includes an arcuate slot (where element 49 passes through) defining a pivot path of the respective said retractor; said engagement member includes a slot (where element A passes through) extending along a longitudinal axis; and said adjustment mechanism further comprises a roller pin (61).

Gauthier discloses the following of claim 60: the system of claim 58, further comprising another of said plurality of retractors attachable to said frame portion generally opposite said retractor (Fig. 1).

Gauthier discloses the following of claim 61: the system of claim 58, wherein at least one of said retractors include a blade portion defining a substantially flat tissue contacting surface (at the upper portion of element B') extending along a longitudinal axis of said blade portion, and at least another of said retractors includes a blade portion defining a concave tissue contacting surface extending along a longitudinal axis of said at least another retractor (at the lower portion of element B').

Gauthier discloses claims 62-67 as shown in Figure 1.

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Gauthier discloses the brackets of claim 68 in element 58.

Gauthier discloses the following of claim 69: the system of claim 58, wherein in an operative position said includes a medial portion adapted, a caudal portion, and a cephalad portion proximate a second end of the medial portion (Fig. 1).

Gauthier discloses the following of claim 70: the system of claim 69, wherein in said operative position at least one of said plurality of retractors is attachable to said medial portion and is positionable adjacent the spinal mid-line, least one of said plurality of retractors is attachable to said caudal portion and is positionable in a caudal orientation relative to the spine, and least one of said plurality of retractors is attachable to said cephalad portion and is positionable in a cephalad orientation relative to the spine (Fig. 1).

Gauthier discloses the following of claim 71: the system of claim 58, further comprising one or more brackets (58) coupled to at least one frame portion configured to attach to a surgical table securing arm to support the system.

Gauthier discloses the following of claim 72: a surgical instrumentation system to provide a surgical approach to a patient's spine, comprising: a frame (F) including a first portion (left side of frame) and a second portion (right side of frame); a plurality of retractors (A, A', B, B') secured to the frame and adapted to pivot relative to the frame, at least one of said retractors being secured to said first portion of said frame and extending transversely to said first portion (Fig. 1) and at least one other of said retractors being secured to said second portion of said frame and extending transversely to said second portion (Fig. 1); and an adjustment mechanism (Fig. 7, 15) for facilitating pivotal adjustment of the retractors; wherein said retractors are secured to the frame with securement devices (11, 13) each including a receptacle being

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slideable along a respective one of said first and second portions of said frame (col. 4, lines 28-36); and wherein each of said retractors is lockable in a selectable pivoting location by engagement of the adjustment mechanism with a portion of the retractor (col. 1, lines 34-47; col. 5, line 65 through col. 6, line 20).

Gauthier discloses the following of claim 73: the system of claim 72, wherein said frame further comprises a third portion (central portion), at least one of said retractors being secured to said third portion of said frame and extending transversely to said third portion (Fig. 1).

Gauthier discloses the following of claim 74: the system of claim 72, wherein at least one of said plurality of retractors include a blade portion defining a substantially flat tissue contacting surface (upper portion of element B') extending along a longitudinal axis of said blade portion, and at least another of said plurality of retractors includes a blade portion defining a concave tissue contacting surface extending along a longitudinal axis of said at least another retractor (lower portion of element B').

Gauthier discloses the following of claim 75: the system of claim 72, wherein at least one of said plurality of retractors include a first side defining a tissue contacting surface (posterior side of elements B, B') and an opposite second side configured to accommodate and support surgical instruments positioned therealong.

Gauthier discloses the following of claim 76: the system of claim 72, wherein at least one of said plurality of retractors include a tissue contacting surface (posterior side of elements B, B') adapted to contact and retract tissue from the surgical approach.

Gauthier discloses the following of claim 77: the system of claim 72, further comprising one or more brackets (58) coupled to at least one frame portion

Response to Arguments

Applicant's arguments with respect to claims 17, 22, 23, 26-31, 34, 37-39, and 58-77 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANN SCHILLINGER whose telephone number is (571)272-6652. The examiner can normally be reached on Mon. thru Fri. 9 a.m. to 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on (571) 272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. S./

Examiner, Art Unit 3774

/DAVID ISABELLA/

Supervisory Patent Examiner, Art Unit 3774